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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/751,344

12/30/2003

Jens U. Quistgaard

021356-000600US

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03/20/2008

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

03/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/751,344	<b>Applicant(s)</b> QUISTGAARD ET AL.	
	<b>Examiner</b> KATHERINE L. FERNANDEZ	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 23 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ng (US Patent No. 5,820,623) in view of Eshel et al. (US Pub. No. 2003/0083536) and further in view of Peterson et al. (US Patent No. 6,126,619) and Front et al. (US Patent No. 6,368,331).

Ng discloses an apparatus for precise positioning of a medical device comprising: a base (28); a robotic articulating arm having a base end attached to said base and an unsecured end (column 4, lines 39-43); a medical device removably attached to said unsecured end with a motor coupled to the device (column 5, lines 6-24; column 13, lines 15-58, column 7, lines 21-27, lines 52-56; column 8, lines 29-34); at least one position sensor located substantially near said unsecured end and capable of determining the precise position of said medical device relative to a patient and said base (106; column 6, lines 38-44; column 8, lines 31-33; column 11, lines 8-11); and a controller wherein the controller utilizes data from said position sensor to control the robotic articulating arm to maintain the location the device relative to the patient (column 11, lines 1-20; column 12, lines 48-54). See Figures 1-2 and 8.

However, they do not specifically disclose that the medical device is a therapy head, the therapy head including a housing, an array of diagnostic and therapeutic

ultrasound transducers contained within the housing, motors coupled to the array, a water circulation system, a plurality of detectors, and an electronic data chip; or that the controller utilizes data from the data chip in the therapy head to control the robotic articulating arm and to maintain the location of the therapy head over the patient body surface. They also do not disclose the limitations of claim 40, wherein the controller automatically identifies the therapy head and provides proper motion information to the robotic arm for movement consistent with an operation design for the therapy head, the operation design parameters being incorporated into the data chip.

Although Ng discloses that surgical tools or diagnostic tools (i.e. a therapy head) can be attached onto the articulated arm (column 5, lines 16-24) and that the diagnostic tool can be an ultrasound probe (column 13, lines 34-47), they do not specifically disclose that the therapy head includes a housing, an array of diagnostic and therapeutic ultrasound transducers contained within the housing, and a plurality of detectors. Eshel et al. disclose a method and system for lysing adipose tissue which includes the steps of directing focused ultrasonic energy at a target volume in a region of a body containing adipose tissue (pg. 1, paragraphs [0007]-[0009]). A transducer (10) which includes a housing, an array of diagnostic (23) and therapeutic (13) ultrasound transducers contained within the housing and a plurality of detectors is attached to an articulating arm (See Figure 1; pg. 3, paragraphs [0060], [0064], [0066]-[0067]; pg. 5, paragraphs [0100]-[0103]). The transducer is positioned on the body over a location within the region containing adipose tissue (pg. 3, paragraph [0072]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to

modify the apparatus of Ng. to have the medical device be a therapy head including a housing, an array of diagnostic and therapeutic transducers contained within the housing, and a plurality of detectors and have the therapy head be positioned over the patient body surface, as taught by Eshel et al., in order to accurately direct and focus ultrasonic energy to a desired region so that the apparatus can be used for therapeutic applications, such as the lysing of adipose tissue (pg. 1, paragraphs [0006]-[0015]). However, the combined references of Ng and Eshel et al. do not specifically disclose a water circulation system and an electronic data chip are included in the housing. They also do not disclose that the controller utilizes data from the data chip in the therapy head to control the robotic articulating arm and to maintain the location of the therapy head over the patient body surface or the limitations of instant claim 40.

Peterson et al. disclose an ultrasonic medical transducer apparatus and method for coupling ultrasonic energy to a body for medical therapy (column 3, lines 17-21). They disclose that the ultrasonic transducer includes a housing, and means for generating ultrasonic waves in response to an electrical signal supplied by an external power source, as well as a front mass disposed in the housing and a radiator for directing the ultrasonic waves into a medical target in a patient (column 3, lines 23-29). A reservoir is provided in the housing for containing a fluid conductive medium, such as water, between the front mass and the body surface of a patient (column 3, lines 31-61; column 6, lines 27-42). They disclose that water is a suitable fluid conductive medium which can be circulated in order to provide protection to healthy tissues (column 3, lines 31-36; column 6, lines 37-42). At the time of the invention, it would have been obvious

to one of ordinary skill in the art to modify the apparatus of Ng and Eshel et al. to have a water circulation system included in the housing, as taught by Peterson et al., in order to couple the ultrasonic waves to the body surface and to provide protection to healthy tissues (column 3, lines 31-36; column 6, lines 37-42). However, the combined references of Ng, Eshel et al. and Peterson et al do not specifically disclose that the housing includes an electronic data chip, or that the controller utilizes data from the data chip in the therapy head to control the robotic articulating arm. They also do not disclose the instant limitations of claim 40.

Front et al. disclose a method and system for guiding a diagnostic or therapeutic instrument towards a target region inside the patient's body (column 1, lines 12-15). Front et al. disclose that an indicator is attached to the instrument and generates data indicative of the indicator position in a 6D coordinate space which is transmitted to a guiding controller (column 8, lines 36-56). They further disclose that the instrument additionally has an identification chip, wherein the chip has an embedded application enabling the identification of the physical dimensions of the specific instrument (column 5, lines 23-33; column 8, lines 57-66). The chip provides data indicative of the instrument's physical parameters, which may be dimensions themselves, or coded data that can be identified by the software installed in the computer (column 8, line 66-column 9, line 7). They disclose that a major factor in the accuracy of a system of the kind specified is exact information on the physical dimensions of a diagnostic or therapeutic instrument associated with a guiding device (column 8, lines 57-62). At the time of the invention, it would have been obvious to one of ordinary skill in the art to

modify the apparatus of Ng, Eshel et al. and Peterson et al. to have the housing include an electronic data chip, have the controller utilize data from the data chip in the therapy head to control the robotic articulating arm, and include the limitations of claim 40, as taught by Front et al., in order be able to identify the physical dimensions of the instrument and thus improve the accuracy of the system (column 8, lines 57-62).

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 23 and 40 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768